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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/594,978 06/15/00 JOHN

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ELAN PHARMACEUTICALS, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
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EXAMINER

L. H. K. T. O. N. D.

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

08/28/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/594,978

Applicant(s)  
Varghese

Examiner  
David Lukton

Art Unit  
1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 2, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-69 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

A restriction is imposed, as set forth below. First, however, the following three subgenera are defined:

**G1:** compounds in this group are limited to those in which substituent variable "A" is limited to (i) on page 72, lines 10-29;

**G2:** compounds in this group are limited to those in which substituent variable "A" is limited to (ii) on page 72, line 30+ ;

**G3:** compounds in this group are limited to those in which substituent variable "A" is limited to (iii) and (iv) on page 73, lines 15-32.

\*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 8-16, 20, 47, 54-62, 66 drawn to compounds, limited to G1.
2. Claims 1, 4-6, 8-16, 19, 20, 47, 50-52, 54-62, 65, 66 drawn to compounds, limited to G2.
3. Claims 1, 7-16, 20-22, 47, 53-62, 66-68 drawn to compounds, limited to G3.
4. Claims 24, 31-39, 43, drawn to a method of using the compounds of Group 1.
5. Claims 24, 27-29 31-39, 42, 43, drawn to a method of using the compounds of Group 2.
6. Claims 24, 30-39, 43-45, drawn to a method of using the compounds of Group 3.

In the event that any of Groups 1-3 is elected, claims 23 and 69 will be joined with that group. In the event that any of Groups 4-6 is elected, claim 46 will be joined with that group.

As is evident, none of claims 2, 3, 17 or 18 has been grouped. It does not appear that claim 2 is subgeneric to claim 1. Claim 2 requires the presence of an  $sp^3$ -hybridized carbon atom which bears an aryl group and a hydroxyl group, but at the same time, there is no carbonyl between that  $sp^3$ -hybridized carbon atom, and the nitrogen atom bearing "A". There is no substituent in claim 1 which corresponds to this. However, judging from claim 3, it appears that the structure in claim 2 is incorrect, i.e., that a carbonyl group is intended. It is perhaps worth noting that the formula in table I (page 25) is not "subgeneric" to formula I of claim 1, i.e., variable "A" is implicitly defined differently in the two cases. At the present time, then, claims 2, 3, 17 and 18 are not grouped. In the event that claim 2 is amended to make clear that it is properly subgeneric to claim 1, claim 2 will be grouped appropriately. The claims corresponding to claims 2, 3, 17 and 18 within the composition and method-of-use claims are also not grouped.

Claim 1 has been sequestered into three groups, depending on the possible substituents of "A". Claim 1 encompasses at least three separate genera; the compounds in each genus are distinct from the others, they will have different properties, and different searches will be required.

Inventions 1-3 and 4-6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(MPEP 806.05(h)). Nevertheless, in the event that any of Groups 1-3 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination [*In re Ochiai* (37 USPQ2d 1127)].

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

✱


In claim 1, on page 73, lines 17-18, the following is recited:

“(including primary, C<sub>1</sub>-C<sub>6</sub> alkyl secondary, C<sub>1</sub>-C<sub>6</sub> alkyl and phenyl tertiary, amino, C<sub>1</sub>-C<sub>6</sub> alkyl and phenyl amino”

However, there is an unmatched left parenthesis, which generates uncertainty about what is being claimed. In addition, applicants are requested to explain the meaning of the following: “phenyl tertiary, amino”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800